

Remarks

Applicants wish to thank Examiner Scott Medway and Supervisory Patent Examiner Nicholas Lucchesi for their courtesy extended in the Interview of June 2, 2009. Applicants' attorney Deanna Shirley discussed the invention, also described below, and the prior art cited in the Office Action, specifically Brock 7,297,142. It was agreed that Applicants' invention can be distinguished from the Brock reference by amending the claims to include the limitation that the distance over which an elongate member is advanced and retracted is not limited by the means for advancing and retracting, and is not limited by the housing. Applicants have accordingly amended their claims to incorporate the foregoing limitation. Applicants have also amended the specification in response to the Office Action as described below.

Applicants' invention is directed to a novel apparatus for manipulating elongate members, especially guide wires and catheters, during medical procedures. One of Applicants' systems includes a rotating housing through which guide wires and catheters can be advanced and retracted. As described in the specification and Figure 22A, an active drive-wheel disk (for advancing and retracting elongate members) is housed within a rotating closed clamshell structure. As illustrated by the clamshell example, numerous considerations for practical and effective manipulation of elongate members (within the parameters of treatment of a patient undergoing a cardiovascular or other procedure) are incorporated into Applicants' invention.

A first consideration is the extensive length of many of these devices. A typical treatment requires elongate devices of substantial length (such as a length of 300 cm) and extensive manipulation over this length, including advancement, retraction, and rotation. In addition, during a typical procedure, devices having *varied* lengths are employed (see published application paragraphs 8-13). Accordingly, it is desirable that an apparatus accommodate elongate devices of different lengths, and that the apparatus does not constrain a practitioner to a particular length. In addition, the devices are quite flexible and smooth surfaced, which, together with the tremendous length of a typical device, require attentive application of force at a focal location not far removed from either the incision site of a patient, or any point at which the devices encounter resistance. And finally, in a typical procedure, more than one type of device may be required to be

“threaded” through an apparatus and/or exchanged with one another in order to complete a procedure. It is undesirable to be required to remove one device from the body of the patient and to subsequently “rethread” the tip of the device through an apparatus before re-entering the incision or other access point into the patient’s body. Accordingly, it is an improvement if an apparatus is configured such that it can be reloaded with an elongate member without rethreading the tip of the elongate member.

It will be appreciated by one skilled in the art that Applicants’ novel apparatus is a structure comprising interrelated elements which operate to allow all of the above referenced manipulations, especially with respect to the considerable length over which such manipulations must be performed. Applicants’ claims have been amended to recite the elements and their interrelationship and to more clearly distinguish over the prior art. In addition, Applicants have amended the specification to overcome the Examiner’s objections thereto. Support for the foregoing amendments can be found in the originally filed specification and claims, for example, at paragraphs 0073, 0082, 0128 and 0129.

Objections to the specification

In the Office Action, the Examiner objected that Applicants have invoked means-plus-function language to define the invention, and requires that the specification be amended to explicitly state the structure, materials, and acts which perform the function recited in the claim element.

The original specification described numerous examples of means for advancing and retracting elongate members. And as each of the illustrated means are iterative, or undergo a cycle which may repeat, the means for advancement and retraction does not limit the distance of advancement and retraction. Several of Applicants’ embodiments incorporate a wheel driven by a motor and coupled to an elongate member to advance and retract the member. In addition, alternative embodiments incorporate other iterative means for advancing and retracting an elongate member, which can operate over a finite length before repositioning to repeat the cycle. One example is a gripper mechanism mounted upon a linear actuator which grasps an elongate member, travels along the linear actuator to advance (or retract) the elongate member, releases the member, and returns to its original position to repeat the cycle as needed (see paragraph 68.) Applicants have amended the specification as required by the Examiner to emphasize that the

embodiments set forth above represent several examples of “means for advancing and retracting an elongate member over a variable distance whereby said distance is not limited by said housing and said distance is not limited by said means for advancing and retracting” as recited in Applicants’ claims.

It will be appreciated by one skilled in the art that utilizing the foregoing means for advancing/retracting an elongate member has the advantage of permitting the advancement/retraction over a large distance. In addition, the exemplary means allow the application force to the elongate member at a narrowly focused site upon the elongate member, as necessary when manipulating a flexible member. Such means are contrasted with, for example, a track-mounted carriage, which may only advance the length of the track, a distance which may be short compared to the length of the member, yet too long when compared with the distance over which a force may be applied given the members’ flexibility and the tendency of a catheter or guide wire to collapse upon itself in loops when pushed forward in unrestricted space outside of a patient’s body. A cycling or iterative means is thereby superior for manipulating elongate members of the lengths characteristic of guide wires, catheters, and other devices used in any of a variety of catheterization procedures, and this advantage is incorporated into the claims by the recitation that the distance over which the members may be manipulated is not limited by the means for advancement or retraction, and is not limited by the housing.

The 102 rejections

In the Office Action, the Examiner rejected claims 8-10 and 13 under 35 U.S.C. 102 as being anticipated by Brock (U.S. Patent No. 7,297,142).

Brock discloses a system for delivering to an internal body site a selected one of a plurality of surgical instruments. The Examiner cites instrument storage chamber 40 and cylindrical chamber 44 as anticipating Applicants’ claims. However, it appears that advancement and retraction of the elongate structures of Figure 2 are effected by movement of carriage 54 along rails 55. Column 8:6 describes “motion of carriage 54 for control of the linear translation of the driver 50”. And it is the rotatable instrument storage chamber 40 which rotates. Carriage 54 and chamber 40 are *separate* structures, and cannot be read to disclose or suggest Applicants housing element, a single structure

in which both rotation about the elongate axis of the member *and* advancement/retraction of the member is effected.

Moreover, Applicants are unaware of any reference in the relevant art disclosing a structure (housing) which is capable of *both* rotation about the axis of the member *and* comprises the means for advancing and retracting an elongate member, where the distance the elongate member is advanced or retracted is not limited by the housing structure. (Applicants file a Supplemental Information Disclosure Statement herewith.)

Applicants have amended independent claim 8 to more clearly set forth Applicants' invention and according to the Examiner Interview. It will be appreciated that according to the invention, the housing that is capable of rotation about the elongate axis of an elongate member is configured to be the SAME housing that includes means for advancing and retracting the elongate member. The foregoing distinction is incorporated in Applicants' amended claim 8, which recites that the apparatus comprises:

...a housing rotatable about the elongate axis and configured to releaseably engage said elongate member, said housing also comprising means for advancing and retracting the elongate member. . .

Further, according to the invention, neither the means of advancement/retraction of the member, nor the housing, limits the distance of advancement/retraction of the member. As explained above, a typical elongate member utilized in a catheter procedure is of significant length. Appropriately, Applicants' invention comprises interrelated elements which are capable of manipulating an elongate member of great length, not limited by either the means for advancement/retraction or the structure of the housing.

For the foregoing reasons, Brock neither discloses nor renders obvious Applicants' invention as set forth in amended claim 8.

Moreover, even if structure 40 or 44 of Brock were read as anticipating a housing as claimed by Applicants', then that housing must be read as limiting the distance over which an elongate member can travel, as carriage 54 can only advance until it comes into contact with structure 40 (See Figures 1 and 2).

Because independent claim 8 is patentable, Applicants submit that all claims depending therefrom are also patentable. Accordingly, Applicants request that the rejection under 35 U.S.C. 102 be withdrawn.

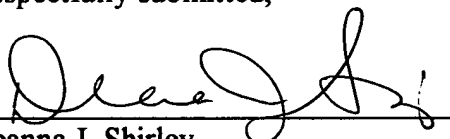
The 103 rejections

In the Office Action, the Examiner rejected dependent claims 11-13 and 21-22. For the foregoing reasons, the foregoing claims are patentable as depending from patentable claims. Accordingly, Applicants request that the rejections based upon 35 U.S.C. 103 be withdrawn.

Conclusion

Applicants thank Examiner Medway and Supervisory Patent Examiner Lucchesi for the courtesy of the Interview June 2, 2009. Applicants have amended their claims and specification in response to the Office Action and Interview. None of the foregoing amendments introduces new matter. Accordingly, Applicants request that the foregoing amendments be entered and that the application be placed in condition for allowance. It is not believed that additional extensions of time are necessary beyond that petitioned for herewith. However, if an extension of time is necessary to avoid abandonment of the application, such extension is hereby petitioned, and it is requested that the undersigned be contacted for any fee deficiency.

Respectfully submitted,



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